Contents

FAQ – Reference material

Subject area	Questions and answers
I. Processing payments	1. **Why is "Bundeskasse Trier" indicated as the account holder?**
	Like all other senior federal authorities, the Paul-Ehrlich-Institut does not hold its own bank account. All bank transactions of the Paul-Ehrlich-Institut are processed via the federal treasury (Bundeskasse) at the Trier location. The latter has an account at the German Federal Bank (Deutsche Bundesbank.
	2. **What is the complete address of the account holder's bank?**
	Deutsche Bundesbank, Filiale Saarbrücken, Hafenstraße 20/21, 66111 Saarbrücken, Germany.
	3. **How high are the bank charges?**
	The bank charges depend on the conditions of the bank commissioned by the customer and must be obtained from that bank by the customer.
	4. **Who will have to bear the bank charges?**
	The customer must bear all bank charges for all banks involved when transferring the invoice amount. For international bank transfers, the customer must check the box "OUR", otherwise the difference will be claimed at a later stage.
	5. **Who is the contact for the bank account at the Paul-Ehrlich-Institut (name, function etc.).**
	Contact: Unit Z2 Finance, Email address: gebuehren@pei.de
	6. **Can invoices from the Paul-Ehrlich-Institut be made up in a currency other than EURO?**
	No. The Paul-Ehrlich-Institut issues its invoices in Euro only.
	7. **Can invoices at the Paul-Ehrlich-Institut be paid in a currency other than EURO?**
	No. The Paul-Ehrlich-Institut accepts Euro as the only currency for the payment of invoices.
	8. **Under what circumstances will an advance payment be required from the customer?**
	An advance payment will be required if the customer is placing his first order, and for all customers outside the European Economic Area, and if a customer haa proved to be unreliable in previous transactions. The decision concerning this is made by Unit Z2 Finance.
	9. **If no advance payment is required, what is the due date for payment?**
	The due date is always indicated on the invoice. For payers in Germany, it is 34 days as from the invoice date, and for international payments, 41 days as from the invoice date.
	10. **Does the Paul-Ehrlich-Institut grant a discount on the invoice amount?**
	No. No discount is granted.
	11. **What mode of payment is possible? Can the invoice be paid by using an agency or institute (e.g. in the event that the client can only pay by credit card)?**
	In principle, payments can be made only by bank transfer. Unfortunately, direct payment by credit card is currently technically not possible at the Paul-Ehrlich-Institut. However, you can use services

I. Processing payments	*such as PayPal, where you can indicate your credit card as means of payment.*
	12. **Who will pay the shipment costs?**
	The ordering party shall bear the full shipment costs.
	13. **Can the shipment costs of the contracted shipper and of the product appear on the invoice from the Paul-Ehrlich-Institut?**
	In principle: No. The ordering party shall pay the shipping costs directly to the shipping company which received the order for shipping.
	14. **Why do customers sometimes still receive invoices for freight costs from the Paul-Ehrlich-Institut?**
	Customers will receive invoices for shipment from the Paul-Ehrlich-Institut if they did not pay the shipment costs for their delivery to the shipment company (see question 13), and the Paul-Ehrlich-Institut bore the costs as a pre-payment service for this reason..
	15. **After how many days delay will reminders be sent to customers?**
	The Paul-Ehrlich-Institut starts sending out reminders one week after the due date for payment. If the customer still does not carry out payment, the seizure of the payment will be started by the customs authorities after the appropriate notification.
	16. **When does the period of payment delay start, which relates to the delay interest and delay flat rate, and how are the delay interests and the delay flat rate calculated?**
	Payment is considered as overdue as from the first day after the due date pursuant to Section 286 para. 2 p. 1 German Civil Code Bürgerliches Gesetzbuch (BGB). In this case, delay interests are incurred based on the amount of the invoice and the number of days of delay are charged plus a flat rate for delays in the amount of 40 EURO pursuant to 288 para. 1 & para. 5 BGB.
	17. **Can the invoice be cancelled, and, if yes, how?**
	Yes, the customer can have the invoice cancelled if the product is no longer desired or no longer deliverable.
	18. **What happens if the Paul-Ehrlich-Institut cannot provide the product ordered within four weeks after receipt of payment?**
	The customer has the right of repayment if, for this reason, he decides to forgo receiving the reference material.
II. Tax information	19. **Can the customer receive tax forms W-8 BEN/ W-8 BEN-E?**
	Yes, these forms can be issued upon request. *The applicable form for the Paul-Ehrlich-Institut can be found under this link https://www.irs.gov/pub/irs-pdf/fw8exp.pdf (foreign governments).*
	20. **Which tax information can be found on our invoices?**
	To what extent taxability applies as well as the applicable tax notes depends on the individual case. For tax law related questions, please contact Unit Z2 Finance on this email address: haushalt@pei.de.
	21. **Who is the contact for tax matters: Member of staff (name, function etc.)?**
	Contact: Unit Z2 Finance, Email: haushalt@pei.de
	22. **Which product tariff numbers (TARIC Code) do the products have?**
	The classification can be performed using the list from the European Commission below:

	https://ec.europa.eu/taxation_customs/dds2/taric/taric_consultation.jsp?Lang=de&Screen=0&redirectionDate=20110124 *Reference material in principle belongs to TARIC Code group 3002. The sub-groups belonging to this group depend on the section at the PEI responsible for this.* *2/4: 30029010 (e. g. infectious blood plasma), 30029050 (e. g. Zika virus)* *3/1: 30021900* *4/3: 30029030* *IVD: 30021900*
III. Ordering modalities	23. **Can the customer receive a quote or participate in a tender bid?**
	A quote will be issued to the customer upon request. However, the Paul-Ehrlich-Institut does not participate in tender bids by the customer.
	24. **Is there a discount system for the products?**
	The Paul-Ehrlich-Institut has determined prices for the individual products. For products #8483/13, #11162/16, #11163/16, #11164/16, #11165/16, #11166/16, #11167/16, #11168/16, #11169/16, #11170/16, #11171/16 a discount is granted for large amounts. Other price agreements are not available.
	25. **In what amount are orders from each customer each year for each product possible?**
	In principle, every customer can order 5 units maximum for each product per year. The Paul-Ehrlich-Institut will decide on exceptions to this rule on a case-to-case basis.
	26. **Which positions will appear on the invoice?**
	The invoice will contain: *1. Amount/product name/price* *2. Costs for packaging/price (product dependent)* *3. 19% VAT if applicable*
	27. **Will an import permission be required?**
	The institute or company ordering the reference materials must have an import permission for the material ordered if such a permission is required in accordance with the regulations of the respective importing country.
	28. **Can the customer become a sub-contractor/general agent for the Paul-Ehrlich-Institut?**
	No. This is ruled out. Das Paul-Ehrlich-Institut has a monopoly with regard to the order on the part of the WHO.
	29. **Is it possible to order via a dealer in the customer's country?**
	No. Only a direct order at the Paul-Ehrlich-Institut is possible.
	30. **Will the customer receive an order confirmation?**
	Yes. However, an order confirmation which was pre-prepared by the customer will not be confirmed.
	31. **Is it absolutely necessary to fill out the order form? Where can the order forms be found?**
	Yes. You will find the order forms on our website: https://www.pei.de/DE/regulation/referenzmaterial/referenzmaterial-node.html (under the tab "Bestellung" (=orders)).

IV. Product information	32. **Is any information and details on the products available?**
	For some of the products, a product information sheet is provided in principle, for others only upon request.
	33. **Is there any information on the manufacture of the products?**
	For some products, information is available on the website of the Paul-Ehrlich-Institut. This especially applies to products provided by the WHO. *For all other products, information can partly made available upon request.*
	34. **Is there any information on the titre and reference range of the products?**
	This can, in some cases, be found in the product information sheet.
	35. **Is there any information on the stability and the expiry date of the products?**
	This can, in some cases, be found in the product information sheet.
	36. **Can standard operating procedures (SOPs) be provided concerning the performance of the tests, the materials ordered, or concerning the publications for qualifying the materials/for the prevalidation of the method?**
	For some of the products, these documents can be provided upon request.
	37. **Can information be provided on the composition of the required culture media?**
	For some of the products, these documents can be provided upon request.
	38. **Are certificates of analysis available on the individual products?**
	Information on this can be provided, product-related, in the product information sheets or the package insert (as applicable) and on our website.
	39. **Is any information provided on the duration of usability?**
	Yes. For some products, this is provided in the product information sheets or the quality control card (as applicable). However, stability tests may still have to be performed.
	40. **Where and when were the products manufactured?**
	Information concerning this can be found in the product information sheets. Existing publications may also be issued upon request. *For WHO products, the appropriate information is available in the WHO BS report. For some products, this is also linked on our website.*
	41. **Is there a safety data sheet for the individual products?**
	No. The package insert contains the appropriate note only for the WHO products.
	42. **Can the customer receive a list of those of our customers who purchased be product?**
	No. For data protection reasons, customer data cannot be disclosed.
V. Shipment modalities	43. **Why do packaging costs have to be paid?**
	The shipment of the products requires specialised types of packaging, partly on dry ice. This is covered by the packaging costs.
	44. **Why are the products often shipped on dry ice?**
	Since the reference material is partly deep-frozen und must remain deep-frozen, shipment on dry ice is absolutely necessary for these

V. Shipment modalities	*products. This is the only method of guaranteeing the quality of the products.*
	45. **Who provides the packaging material and the dry ice?**
	As a rule, the Paul-Ehrlich-Institut will provide the packaging material and the dry ice. In some cases, the dry ice will be provided by the shipping company, who will charge a fee for this.
	46. **What conditions have to be observed for the shipping of the products with dry ice?**
	The transport temperature of the product must be guaranteed. The required amount of dry ice is calculated depending on the distance the product travels, or topping up with dry ice by the shipper is agreed upon with the shipping company.
	47. **Can reference materials from different areas at the Paul-Ehrlich-Institut be shipped together?**
	Yes, providing the products are ordered in a timely manner, or the shipment is prepared simultaneously.
	48. **Can the customer order his own shipping company?**
	Yes, but only in agreement with the Paul-Ehrlich-Institut. The shipping company and the customer will then take on all the responsibilities required for shipment. This can only be achieved by certain shipping companies.
	49. **Who will perform the declaration for the shipment? (e. g. sender's and recipient's contact details, description of the contents, dimensions and weight, number of vials, and other additional information for customs purposes)**
	The Paul-Ehrlich-Institut will assume the job of the declaration.
	50. **Can any technical information be provided on the products (Technical Data Sheets)?**
	Technical information is partly available in the product sheets or can be provided upon request.
	51. **What are the international trade clauses used by the Paul-Ehrlich-Institut (Incoterms)?**
	The Paul-Ehrlich-Institut will deliver ex works (EXW) and to the site of delivery in the import country (DAP).
	52. **What happens if the products become unusable on the transport route?**
	Should the recipient notice any faults on the product, he shall report this to the PEI immediately, however, withing three working days maximum after receipt. Liability matters shall be clarified subsequently on a case-to-case basis based on the current situation.
	53. **Are urgent deliveries possible?**
	In individual cases, urgent deliveries can be performed upon request.
VI. Product quality	54. **Are the reference materials of the Paul-Ehrlich-Institut CE marked?**
	The Paul-Ehrlich-Institut will provide CE numbers for its own material. IVD material is material which the Paul-Ehrlich-Institut produces in the name of the WHO. Such products do not require CE marking and do not fall within the IVD Directive. The testing laboratory of the PEI – in vitro diagnostic devices (IVD) – performs product testing pursuant to Directive 98/79/EC.

	https://www.pei.de/DE/regulation/referenzmaterial/referenzmaterial-node.html
	55. **Will batch certificates be issued for the reference materials?**
	No, this is not done.
	56. **How does the Paul-Ehrlich institute organise the recall of defective goods?**
	Recalls do not take place.
	57. **How does the Paul-Ehrlich-Institut organise the replacement of defective goods?**
	In the case of faulty products, e.g. broken ampoules or incorrect products, the products are replaced free of charge. If the product has already been received by you in a faulty state, please report this to the PEI without delay, however, after three days at the latest.

FAQ – Quality management and Certification

VII. Quality management and Certification	58. **Is there a qualified quality management system at the Paul-Ehrlich-Institut as well as standard operating procedures (SOPs)?**
	The Paul-Ehrlich-Institut has undergone continued accreditation processes pursuant to ISO 17025 to prove its competency as a testing laboratory since 1999. The Paul-Ehrlich-Institut is not accredited for the production of reference materials (ISO 17034). The QM system and the QM manual are characterised by the standard requirements of ISO 17025. Information on the quality management can be found by visiting this webpage: https://www.pei.de/DE/regulation/qm/qualitaetsmanagement-inhalt.html; For an overview of the test methods accredited by the DAkkS (Deutsche Akkreditierungsstelle, German Accreditation Body), please follow this link: https://www.pei.de/SharedDocs/Downloads/DE/regulation/qm/qm-leistungsverzeichnis.pdf?__blob=publicationFile&v=7
	59. **Do document batch certificates exist at the Paul-Ehrlich-Institut?**
	In principle, allergens, products manufactured from blood plasma, immunoglobulins, and vaccines are subject to official batch testing pursuant to Section 32 AMG (Arzneimittelgesetz, German Medicines Act). Batch certificates are issued on the basis of valid test series, on the basis of defined release criteria for conformity to the specifications laid down in the marketing authorisation and pursuant to pharmacopoeia requirements. The link to batch testing can be found here: https://www.Paul-Ehrlich-Institut.de/DE/regulation/chargenpruefung-human/cp-hum-node.html
	60. **Do documented regular staff trainings take place at the Paul-Ehrlich-Institut?**
	The requirements for the documentation of staff training conform to the standard requirements of DIN EN ISO 17025 for proof of the competency of the personnel in the test laboratory.
	61. **Does the Paul-Ehrlich-Institut have documented regular product quality tests?**
	1.CAP Testing: *The EMA bears the responsibility for monitoring the medicines authorised by means of the centralised marketing authorisation with regard to their quality. For this reason, EMA created the "Centrally Authorised Products (CAP) sampling and testing programme" in 1999. The supervisory programme is performed annually be the EDQM in cooperation with the OMCL network upon request from the EMA. Samples of the medicines to be tested from three member states are drawn by inspectors. After that, the medicines selected are tested by control for agreement with the appropriately authorised specifications by the OMCLs determined for this (two OMCLs per medicine).* *2. Official batch testing pursuant to Section 32 AMG (Arzneimittelgesetz, German Medicines Act):* *See also the information under "Documented batch certificates"*

VII. Quality management and certification	*Regular participation in collaborative trials. For methods in the field of accreditation, suitability tests are performed in order to ensure continued quality. A 5-year plan is in place for this, which is periodically updated.* *WHO International Standards and WHO Reference Material Panel: Stability programme*
	62. **Does the Paul-Ehrlich-Institut provide documented regular maintenance and calibration of plant and equipment?**
	The equipment and test media used for testing within ISO 17025 are purchased and qualified in accordance with the quality principles of design qualification (DQ), installation qualification (IQ), operation qualification (OQ), and performance qualification (PQ). For the equipment and the test media, all quality relevant records are managed in the appropriate equipment log books. Handling the equipment and preparing and managing the equipment log books is laid down in internal operating procedures. *Maintenance plans are monitored in an equipment databank and the documentation is managed in the responsible organisational units in log books.*
	63. **Does the Paul-Ehrlich-Institut provide documented regular maintenance of the rooms?**
	Tests and all other activities relating to this are performed in suitable laboratory rooms, which meet the requirements from the construction and technical point of view. Environmental conditions are monitored, documented, and, if required, adapted in a suitable manner. *Operation and maintenance of the technical equipment, room air technology and electrical and technical plants as well as alarm devices are the responsibility of Unit Z4.*
	64. **Does the Paul-Ehrlich-Institut provide a documented validation of critical process steps?**
	The validation of test procedures is carried out pursuant to ICH Guideline Q2R Validation of Analytical Procedures: Text and Methodology and pursuant to the VICH Guidelines. The documentation is performed pursuant to the requirements of DIN EN ISO 17025.
	65. **Are there any certifications and standards at the Paul-Ehrlich-Institut? ISO, GMP, others?**
	The accreditation as testing laboratory is performed pursuant to DIN EN ISO 17025, the attestation as testing laboratory (OMCL) is performed by the EDQM
	66. **By whom is the Paul-Ehrlich-Institut audited?**
	External supervision by the DAkkS (Deutsche Akkreditierungsstelle, German Accreditation Body) and by means of Mutual Joint Audit (MJA) by the EDQM on the basis of ISO 17025. *DAkkS is the national accreditation body of the Federal Republic of Germany. It performs its duties pursuant to Regulation (EC) No. 765/2008 and the Act Governing Accreditation Bodies (Akkreditierungsstellengesetz, AkkStelleG) in the public interest as the sole service provided for accreditations in Germany.* *Mutual Joint Audits (MJAs) are an integral part of the QM programme of the "European Directorate for the Quality of Medicines & HealthCare" (EDQM). They were introduced in 1997 within the framework of the "Official Control Authority Batch Release" (OCABR) in the European*

	OMCL network on the basis of the DIN EN ISO/IEC 17025 requirements. The reason was the increasing demand for a standardised exchange of results and test reports. Since 1999, activities of the EDQM have been intensified to advance the harmonisation of the quality policy of the OMCLs and the continuity of the established QM systems. The Paul-Ehrlich-Institut has participated in the EDQM audits since 2012.
	67. **Who performs the inspections? (e.g. district council, Paul-Ehrlich-Institut, Federal Institute for Drugs and Medical Devices (BfArM), others)**
	DAkkS as the national accreditation body of the Federal Republic of Germany. This body acts in accordance with Regulation (EC) No. 765/2008 and the Act governing Accreditation Bodies (Akkreditierungsstellengesetz, AkkStelleG) in the public interest as the sole service provider for accreditations in Germany. *Mutual Joint Audits (MJAs) form an integral part of the QM programme of the "European Directorate for the Quality of Medicines & HealthCare" (EDQM).*
	68. **As a customer, am I permitted to perform audits on site at the Paul-Ehrlich-Institut?**
	Up to now, the usual practice has been that only other European test laboratories, the EDQM and the DAkkS perform audits at the Paul-Ehrlich-Institut. Audits can be contractually accepted in specific situations and within a placement of sub-contracts after consent of the institute's management.
VII. Quality management and certification	69. **Does the Paul-Ehrlich-Institut co-operate with the Food and Drug Administration (U.S. FDA)?**
	Yes, the Paul-Ehrlich-Institut co-operates with the FDA with regard to various different subjects *Examples include the regulation of the ATMPs, development and clinical process of DNA vaccines or combating Zka virus infections (graduated plan procedures).*
	70. **Is the Paul-Ehrlich-Institut certified pursuant to DIN EN ISO 9001 or is such a certification forthcoming?**
	No.
	71. **Does the Paul-Ehrlich-Institut have a document management system?**
	To ensure that the work is performed in accordance with valid specifications both in the regulatory and in the administrative field, QM documents are provided in a QM portal based on SharePoint. The QM document management is subject to the specifications of DIN EN ISO 17025. It is audited internally and externally. A document management system (electronic workflow and document management system) is also used in the administrative and purely regulatory area.
	72. **Do regular internal audits take place?**
	On the basis of ISO 17025, the institute regularly checks internally whether processes meet the requirements of the QM manual and the other instructing documents at the institute. During the overall planning of the internal audits, care is taken that all standard elements are audited within the year.
	73. **Is there a complaint management system to follow up customer's complaints?**

	Appropriate response is provided to complaints for customers, unfavourable feedback, and information pointing to mistakes and omissions in test procedures, as well as any activities relating to these. The mistake which occurred will be corrected as soon as possible, and care will be taken that such errors will not occur in the future. Recording and managing complaints is laid down in internal SOPs. Documenting and performing the necessary steps is reviewed in audits on a regular basis and evaluated in annual QM audits.
	74. **Is there a programme for corrective and preventive action?**
	CAPA is an instrument of the quality management for the lab areas of the Paul-Ehrlich-Institut. It is integrated in the internal audit system on the basis of DIN EN ISO/IEC 17025. It refers to a record in the form of a centrally determined CAPA list, in which a documented review is carried out of any discrepancies (= CAPA case) of the ongoing laboratory operations and the necessary preventive action.
	75. **Are there any procedures in place on site by which changes / deviations of the material, the manufacturing process, the test methods and the product specifications can be controlled?**
	Deviations of test methods are followed up on the basis of ISO 17025.
	76. **Are there any measures on site for: controlled incoming products in the lab, health, and hygiene?**
	The labs are accessed using magnetic cards (access control). The hygiene plan in its current version is put up in each laboratory and is implemented. The required materials (e.g. disinfectants) and technical facilities e.g. hand-wash basins) are provided.
	77. **Is the equipment used maintained an calibrated on a regular basis?**
	All refrigerators and freezers used for storage of products in the testing laboratory are temperature-monitored. The laboratory equipment for product quality control is calibrated, maintained, and monitored according to the QM regulations.
	78. **Are there any decontamination regulations on site?**
	Yes, the regulations are laid down in the currently applicable hygiene plan.
	79. **Is there a waste disposal system on site?**
	Yes, all waste is sorted on site in compliance with the applicable regulations for laboratory waste, then disposed of or inactivated by autoclaving, as required.